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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,559	03/07/2002	Yasushi Ochiai	4367-0101P	9100

2292 7590 02/25/2004

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EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,559

Applicant(s)

OCHIAI ET AL.

Examiner

Rachel M. Bennett

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierre et al. (US 5300318).

Applicants claim a method of manufacturing a drug granule, comprising a granulation step of spraying a solution of a water soluble drug on a crystal of said water soluble drug.

Pierre discloses alimentary and/or medicinal active principles intended for feeding or treating ruminants are polished by spraying a solution of one or more active principles, resins and/or sugars onto the said active principles. The polished active principles are then coated with a polymer providing protection in the rumen. See abstract. It is preferred to employ a solution of sprayed onto a lysine and/or methionine granulate. The base granulate which is subjected to the polishing operation may be made from lysine hydrochloride crystals. The active principle is generally an amino acid such as methionine, lysine or one of its salts, phenylalanine, histidine, arginine, or tyrosine, a medicament such as a vitamin, antibiotic, or antiparasitic agent, or a protein. The diluents and fillers may be sugars, cellulose and/or silica. The granulate is screened so as to retain a granulate distribution between 200 and 4000 μm and preferably between 500 and 2500 μm . The coating contains at least one component which is chosen from basic polymers,

Art Unit: 1615

copolymers, or mixtures. See cols. 1 and 2. The coating mixture solution is sprayed onto the polished granulate using a fluidized bed or any other spraying apparatus. The granulate obtained after coating exhibits increased stability. See col. 3 and claims 1-17. The reference is silent with regards to the granular strength.

While the reference is silent regarding granular strength, differences in granular strength will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such granular strength is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The reference teaches a drug granule, comprising a granulation step of spraying a solution of a water soluble drug on a crystal of said water soluble drug and further coating said drug granule with a release control film coating agent. Therefore, absent unexpected results, it would be obvious to one of ordinary skill in the art to optimize the granular strength because Pierre desires a stable granulate.

Response to Arguments

3. Applicant's arguments filed 11/25/03 have been fully considered but they are not persuasive.

Applicants argue the prior art does not provide any suggestion regarding granular strength. The examiner refers to the reference, wherein it teaches a drug granule, comprising a granulation step of spraying a solution of a water soluble drug on a crystal of said water soluble drug and further coating said drug granule with a release control film coating agent. While the reference is silent regarding granular strength, differences in granular strength will not support the patentability of subject matter encompassed by the prior art unless there is evidence

Art Unit: 1615

indicating such granular strength is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Therefore, absent unexpected results, it would be obvious to one of ordinary skill in the art to optimize the granular strength because Pierre desires a stable granulate. Thus, the rejection is maintained.

Oath/Declaration

4. The Declaration under 37 CFR 1.132 filed 11/25/03 is insufficient to overcome the rejection of claims 1-14 based upon Pierre et al. (US 5300318) as set forth in the last Office action because: It refers only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1615

Correspondence

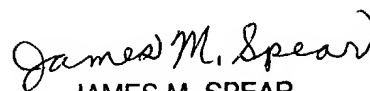
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (571) 272-0589.

The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmb


JAMES M. SPEAR
PRIMARY EXAMINER
Au 1615